

COVID 19 Vaccine Implementation Task Force

Clinic Reference

Title:	COVID-19 Vaccine SPIKEVAX™ (Moderna) Quick Reference for Immunizers
Area:	Reference for Immunizers
Effective Date:	February 5, 2021
Revised Date:	November 15, 2021
Approver:	FINAL

SPIKEVAX™ (Moderna): elasomeran mRNA vaccine indicated for active immunization against coronavirus disease 2019 (COVID-19)

Disclaimer: this Quick Reference is not intended to replace other **product specific** vaccine references but simply lists some frequently referred to information. Please refer to the product monograph and other SPIKEVAX™ specific resources for all current and complete information.

Product Monograph: <https://covid-vaccine.canada.ca/info/pdf/covid-19-vaccine-moderna-pm-en.pdf>

SPIKEVAX™ (Moderna)	Indication (age group)	Latex and Thimerosal-free	Supplied/Storage	Preparation/Administration
elasomeran mRNA vaccine	Approved for 12 years of age and older HOWEVER: Manitoba public health officials continue to recommend that a complete series with CO-MIRNATY™ (Pfizer) COVID-19 vaccine be offered to eligible adolescents 12 to 17 years of age who do not have contraindications to the vaccine where feasible Refer to Government of Manitoba	The vial stopper does not contain natural rubber latex. Fluro Tec-coated chlorobutyl elastomer stopper, 20 mm flip-off aluminum seal Preservative free	Multiple dose vial; supplied as either 5 mL containing 10 full doses; or 8 mL containing 14 full doses. Must be thawed before use. Does not require reconstitution Store frozen between -25°C to -15°C Store refrigerated between 2°C and 8°C for up to 30 days prior to first use. Unpunctured vials may be stored between 8°C and 25°C for up to 24 hours (24 hours is the total amount of time the vaccine may remain at room temperature). Once punctured, vial can be stored at room temperature or refrigerated but must be used within 24 hours (if vial was left at room temperature prior to vial being punctured).	Inspect vials: White/off-white dispersion and may contain white or translucent product-related particulates. If solution contains foreign particulates or discolouration, do not administer. Primary Series (dose 1 and dose 2): 0.5 mL (100 mcg) dose IM deltoid 2 doses - 8 weeks apart (recommended interval); 28 days (authorized interval) Booster dose (dose 3): Administered IM, at least 6 months after dose 2 – please refer to current Provincial eligibility and dosing interval For adults aged ≤ 69 years who are living in community: administered as 0.25 mL (50 mcg) dose

	website for current eligibility criteria		tured, this amount of time goes toward the total allotted time of 24 hours at room temperature). Do not refreeze once thawed. If necessary to transport non-punctured thawed vaccine vials (2-8°C), total transportation time should be no longer than 12 hours. Minimize shaking/vibration. The transit time is considered part of the 30 days allowed at refrigerator temperatures.	- For adults aged ≥ 70 years who are living in community: administered as 0.5 mL (100 mcg) dose - For adults of any age who are living in a personal care home or congregate elderly person housing site: administered as 0.5 mL (100 mcg) dose Protect vaccine from sunlight. Do not shake. Once vial punctured, discard unused vaccine after 24 hours. Maximum number of vial punctures permitted is 20. After 20 punctures, vial should be discarded
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Key Point Summary

Dosage for Primary Series (dose 1 and dose 2): 0.5 mL, intramuscular (IM) in deltoid.

To maximize the number of doses obtained from the multi-dose vial, the following syringes should be used for each vial type:

- 5 mL vial containing 10 doses – use 3 mL syringe
- 8 mL vial containing 14 doses – use 1 mL syringe

Two Dose Primary Series Regime: two, 0.5 mL doses

- **optimal (recommended)** interval of 8 weeks
- **authorized minimum** interval of 28 day
- **minimum** interval of 21 days

While the **optimal (recommended)** interval is preferred, if a person presents for an immunization and would otherwise not return within the **optimal (recommend)** interval, the immunizer may proceed with second dose vaccination if the **authorized minimum** interval of 28 days has passed, provided the first dose product received was an mRNA vaccine (COMIRNATY™ or SPIKEVAX™). The **minimum** interval of 21 days is not recommended; however, would be considered a valid dose in PHIMS.

Please note that the date the first vaccine was administered is considered “day 0” when counting minimum intervals.

Interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series.

Guidance on COVID-19 Second Doses

NACI recommends:

- A person who received a first dose of an mRNA vaccine (COMIRNATY™ or SPIKEVAX™) should be offered the same mRNA vaccine for their second dose.
 - If the same mRNA vaccine is not available or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series.
 - If a different mRNA vaccine is given as a second dose with appropriate spacing, both doses are considered valid and the series complete.
 - Manitoba recommends that young people age 12 - 17 years receive COMIRNATY™ (Pfizer) for both doses as Manitoba has ample supply as well as more experience and safety data in this age group with COMIRNATY™.
- A person who received a first dose of VAXZEVRIA™ (AstraZeneca)/COVISHIELD is recommended to receive an mRNA vaccine (COMIRNATY™ or SPIKEVAX™) for dose two, eight to 12 weeks apart, with an absolute minimum interval of 28 days.

Refer to [COVID-19 Second Dose Interval Quick Reference](#) for recommended and minimum dosing intervals.

SPIKEVAX™ Booster/Third Dose Regime and Dosing Information:

Please refer to [Province of Manitoba | Eligibility Criteria \(gov.mb.ca\)](#) for the most up to date information on additional/third/booster doses eligibility criteria.

Manitoba Health's recommended interval between dose 2 and booster/third dose is a minimum of 6 months with the following exceptions:

- for individuals who are moderately to severely immunocompromised due to a medical condition and/or treatment, recommended third dose of SPIKEVAX™ at ≥ 28 day interval after dose 2
- for individuals who have only received one or two doses of a vaccine that is not approved by Health Canada, recommended dose of mRNA ≥ 28 day interval after last dose

Please refer to [Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers](#) for recommended interval practice for booster/third doses.

SPIKEVAX™ Dosage for Booster/Third Dose:

- For adults aged ≤ 69 years who are living in the community: **administer a half dose of 0.25 mL (50 mcg)**, intramuscular (IM) in deltoid.
- For adults ≥ 70 years who are living in the community: **administer a full dose of 0.5 mL (100 mcg)**, intramuscular (IM) in deltoid.

- For adults of any age who are living in a personal care home or congregate elderly person housing site: **administer a full dose of 0.5 mL (100 mcg)**, intramuscular (IM) in deltoid.

Either mRNA vaccine (COMIRNATY™ or SPIKEVAX™) can be provided for booster/third dose, but whenever possible the same mRNA vaccine should be used as was used for dose two. If the last dose administered was a viral vector vaccine (VAXZEVRIA™/COVISHIELD), either COMIRNATY™ or SPIKEVAX™ should be administered for the third/booster dose.

Efficacy: 14 days after dose 2 was 94.1% effective in the short-term in preventing people from getting lab-confirmed COVID-19. In participants 65 years of age and older, efficacy was 86.4%.

Vaccine effectiveness against COVID-19 variants of concern is evolving. Current emerging data suggests the vaccines offer some level of protection against variants of concern although this varies by vaccine and variant.

Contraindications:

- Acute severe febrile illness – postpone until recovered
- Pediatrics – the safety and efficacy of SPIKEVAX™ in children under 12 years of age has not yet been established

Allergies

Refer to [Manitoba COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers – Appendix C](#) for precautionary information on national guidance related to allergic responses to vaccines.

1. **Allergic to active substance or any of the ingredients in the formulation, or history of a severe allergic reaction after the first dose of any COVID-19 vaccine.** *Refer to medical and non-medical ingredients listed below.

Action: Do NOT immunize individuals with allergies to the active ingredient or any ingredient in the formulation, including non-medicinal ingredient, or container component of the COVID-19 SPIKEVAX™ Vaccine; do NOT immunize individuals with a history of a severe allergic reaction after the first dose of any COVID-19 vaccine.

2. **Mild to moderate immediate allergic reaction (defined as limited in the scope of symptoms and involvement of organ systems or even localized to the site of administration) after previous dose of COVID-19 vaccine or any of its components.**

Action: Vaccination may be considered if a risk assessment deems that the benefits outweigh the potential risks for the individual; and if informed consent is provided. Assessment by a physician or nurse with expertise in immunization may be warranted prior to re-immunization. Risk assessment must be completed and if vaccination is chosen, 30 minute extended observation period post-vaccination should be provided.

3. **Proven severe allergic reaction (example: anaphylaxis) to injectable therapy not related to a component of authorized COVID-19 vaccines (e.g. intramuscular, intravenous, or subcutaneous vaccines or therapies).**

Action: May be routinely vaccinated and do not need to be assessed. An extended period of observation post-vaccination of 30 minutes should be provided.

4. **Suspected but unproven allergy to a vaccine component (e.g. PEG).** *Refer to medical and non-medical ingredients listed below.

Action: May be routinely vaccinated and do not need a specific assessment regarding this suspected allergy. An extended period of observation post-vaccination of 30 minutes should be provided.

5. **History of allergy (including anaphylaxis) not related to a component of authorized COVID-19 vaccines or other injectable therapy (example: foods, oral medication, insect venom or environmental allergens).**

Action: Vaccinate without any special precautions. Client should be observed for a minimum of 15 minutes following vaccination.

***Medical and non-medical vaccine ingredients:**

Ask specifically about allergies to: polyethylene glycol (PEG), polysorbate and tromethamine. (Bowel prep products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens solutions, skin care products, and as additive in some food/drinks, contrast media).

Medicinal ingredient:

- mRNA, encoding the pre fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2)

Non-medicinal ingredients:

- 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)
- Acetic acid
- Cholesterol
- Lipid SM-102
- PEG2000 DMG 1,2-dimyristoyl-racglycerol, methoxy-polyethyleneglycol
- Sodium acetate trihydrate
- Sucrose
- Trometamol
- Trometamol hydrochloride
- Water for injection

Precautions:

Anaphylaxis

- In case of rare anaphylactic events, have appropriate medical treatment readily available post vaccine administration.

Myocarditis and Pericarditis

- Very rare cases of myocarditis and pericarditis have been reported following vaccine administration. These cases occurred more commonly after the second dose and in adolescents and young adults. Typically, the symptom onset has been within a few days after vaccine administration.

- Informed consent should include a discussion of the very rare risk of myocarditis and/or pericarditis following immunization. Individuals should be advised to seek immediate medical attention if they develop symptoms which may include chest pain, shortness of breath, or the feeling of a fast, pounding or fluttering heartbeat.
- As a precaution, NACI recommends that individuals who experienced myocarditis and/or pericarditis after a first dose of an mRNA vaccine should wait to get their second dose until more information is available.

Hematologic -Bleeding

- Vaccine should be given with caution in individuals with bleeding disorders, such as haemophilia or on anticoagulant therapy, to avoid the risk of haematoma following the injection, and when benefit clearly outweighs risk of administration.

Syncope/Fainting

- Can occur with any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from fainting and manage syncopal reactions.

Special Populations:

Refers to clients who:

- are immunosuppressed due to disease or treatment
- have an autoimmune condition
- are pregnant
- are breast-feeding

For the following special populations, please refer to and follow [Manitoba's COVID-19 Vaccine: Clinical Practice Guidelines for Immunizers and Health Care Providers](#).

[Provincial factsheets](#) provide information on the vaccine risks and intended benefits.

NACI recommends that a complete COVID-19 vaccine series **should be offered to individuals in one or more of the above special populations if informed consent includes discussion about the evidence on the use of COVID-19 vaccines in the respective population.** The appropriate section of the COVID-19 Vaccine Consent Form requires a signature from the Immunizer and/or health care provider indicating the Manitoba specific recommendations and policies have been met.

Storage:

Store frozen between -25°C to -15° C until expiration date.

Please note: Health Canada has authorized a 2-month shelf life extension (from 7 months to 9 months) for certain lots of the SPIKEVAX (Moderna) vaccine. This extension applies to lots of US labelled vaccine supplies (supply offered in an 8 mL vial fill containing 14 doses (US label maximum 15 doses) of 0.5 mL each.

<u>U.S. COVID-19 Vaccine Moderna – Lot and Expiry Information</u>			
Lot #	Expiry Date	Fill Volume	Doses per Vial
052C21A	10 Nov 2021	8 mL	14 (US label max. 15)
042D21A	07 Feb 2022	8 mL	14 (US label max. 15)

043D21A	09 Feb 2022	8 mL	14 (US label max. 15)
044D21A	10 Feb 2022	8 mL	14 (US label max. 15)
045D21A	11 Feb 2022	8 mL	14 (US label max. 15)
085D21A	19 Feb 2022	8 mL	14 (US label max. 15)
092D21A	13 Feb 2022	8 mL	14 (US label max. 15)
093D21A	14 Feb 2022	8 mL	14 (US label max. 15)
016E21A	01 Mar 2022	8 mL	14 (US label max. 15)
018E21A	03 Mar 2022	8 mL	14 (US label max. 15)
019E21A	02 Mar 2022	8 mL	14 (US label max. 15)
020E21A	04 Mar 2022	8 mL	14 (US label max. 15)
047E21A	06 Mar 2022	8 mL	14 (US label max. 15)
016F21A	21 Mar 2022	8 mL	14 (US label max. 15)

Preparation

Thawing Vaccine:

- Thaw vaccine in refrigerated conditions between 2°C to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw vaccine at room temperature (15°C to 25°C) for 1 hour.
- Do not refreeze vials after thawing.

Expiration Points:

- Thawed vaccine can be stored in the fridge (2°C to 8°C) up to 30 days prior to first use.
- Thawed, unpunctured vials can be stored at room temperature (8°C to 25°C) for up to 24 hours (24 hours is the total amount of time the vaccine may remain at room temperature (either in an unpunctured vial, a punctured vial, or in a pre-loaded syringe)).
- Punctured vials can be stored at room temperature or refrigerated but must be used within 24 hours. (If a vial was left at room temperature prior to vial being punctured, this amount of time goes towards the total allotted time of 24 hours at room temperature.) Any unused vaccine must be discarded after 24 hours.
- Pre-loaded syringes can be stored at room temperature or refrigerated and must be used before the end of the clinic.
- The maximum number vial punctures permitted is 20. After 20 punctures, the vial should be discarded.
- Moderna vaccine supplied in 14 dose vials has a barcode/QR code on the vial instead of an expiry date. To identify the expiry date, you will need to scan the bar code with a smart device to access the website which will indicate the expiry date. Do not use this vaccine after the expiry date stated. The expiry date refers to the last day of that month.

Administration/Route:

- No reconstitution required.
- Inspect vial – may contain white or translucent product-related particulates. If foreign particulates or discolouration, do not administer.
- Swirl vial gently after thawing and between each withdrawal. Do NOT shake.
- Clean the vial stopper with a single use antiseptic swab and allow to dry.
- Withdraw appropriate dose of vaccine into syringe. A single 25G needle can be used both to draw up and administer the vaccine.

- Administer immediately (IM into deltoid) and no later than 24 hours after vial first punctured or brought to room temperature (whichever time is earlier).
- Record the date and time of first puncture on vaccine vial label.
- If more than the expected doses are drawn from a vaccine vial (greater than 10 or 14 doses depending on how the vial is supplied), vaccine can be administered provided the full dose can be drawn from one vial (do not pool vaccine from multiple vials), all infection control practices have been maintained, and inventory is updated accordingly.

Client Teaching Points:

- Ensure informed consent is obtained.
- Address client's questions.
- Explore history of fainting with immunization/medical procedures.
- Ensure second dose/booster dose interval awareness.
- Inform expected/normal adverse reactions are usually mild or moderate in intensity and resolve within a few days after vaccination: Clients 18-65 years of age were more likely to experience than those over 65 years of age.
 - Common/very common side effects: Pain at the injection site, tiredness, headache, muscle ache and stiffness, chills, fever, swelling or redness at the injection site, nausea and/or vomiting, enlarged lymph nodes.
- Provide [Vaccine Reaction Fact Sheet/information](#).
- Encourage vaccinated clients to continue with all provincially recommended COVID-19 prevention strategies (e.g. staying home when sick, practicing physical distancing, etc.), as there is very limited data regarding asymptomatic transmission following immunization.
- Accessing immunization record
 - Manitobans who have received the COVID-19 vaccine can now access their immunization record online at: <https://sharedhealthmb.ca/covid19/test-results>
 - If clients do not have a health card or an email address, or cannot access their records online, they can complete the COVID-19 Immunization Record Request electronic form at <https://forms.gov.mb.ca/covid-immunization-record-request/>, or can be advised to call 1-844-MAN-VACC (1-844-626-8222).

FINAL		
Date	Name / Title	Signature
January 15, 2021	Dr Tim Hilderman and Dr. Richard Baydack	